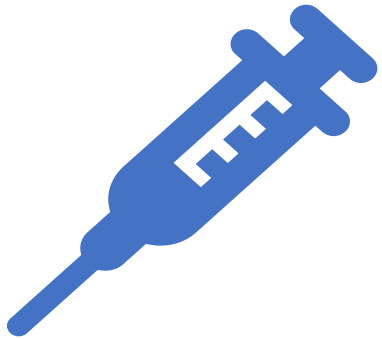
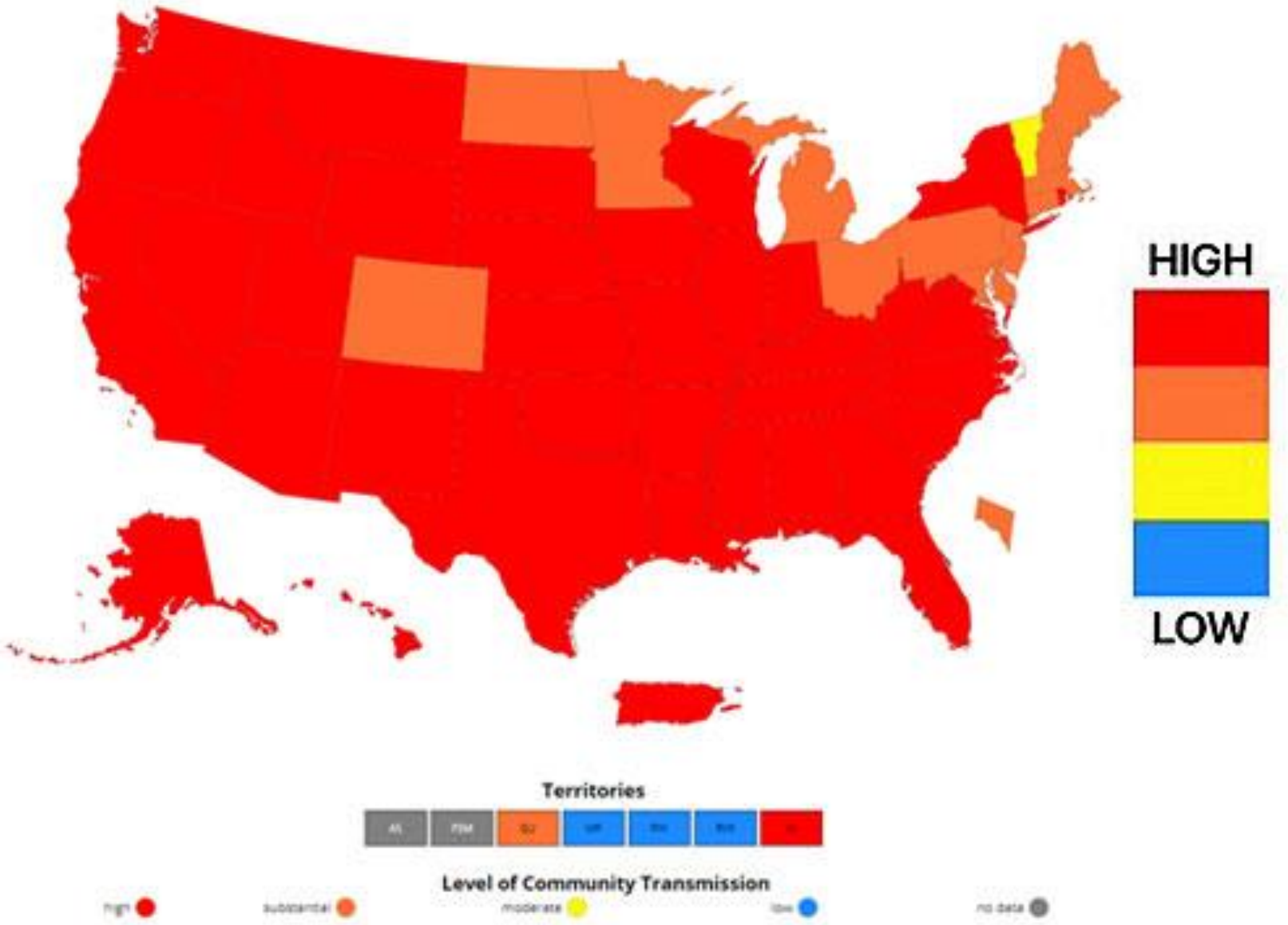
COVID and Pregnancy: the Delta Variant, Vaccination and mAB Treatment



SC BOI Monthly Webinar

August 11, 2021

United States Levels of Community Transmission

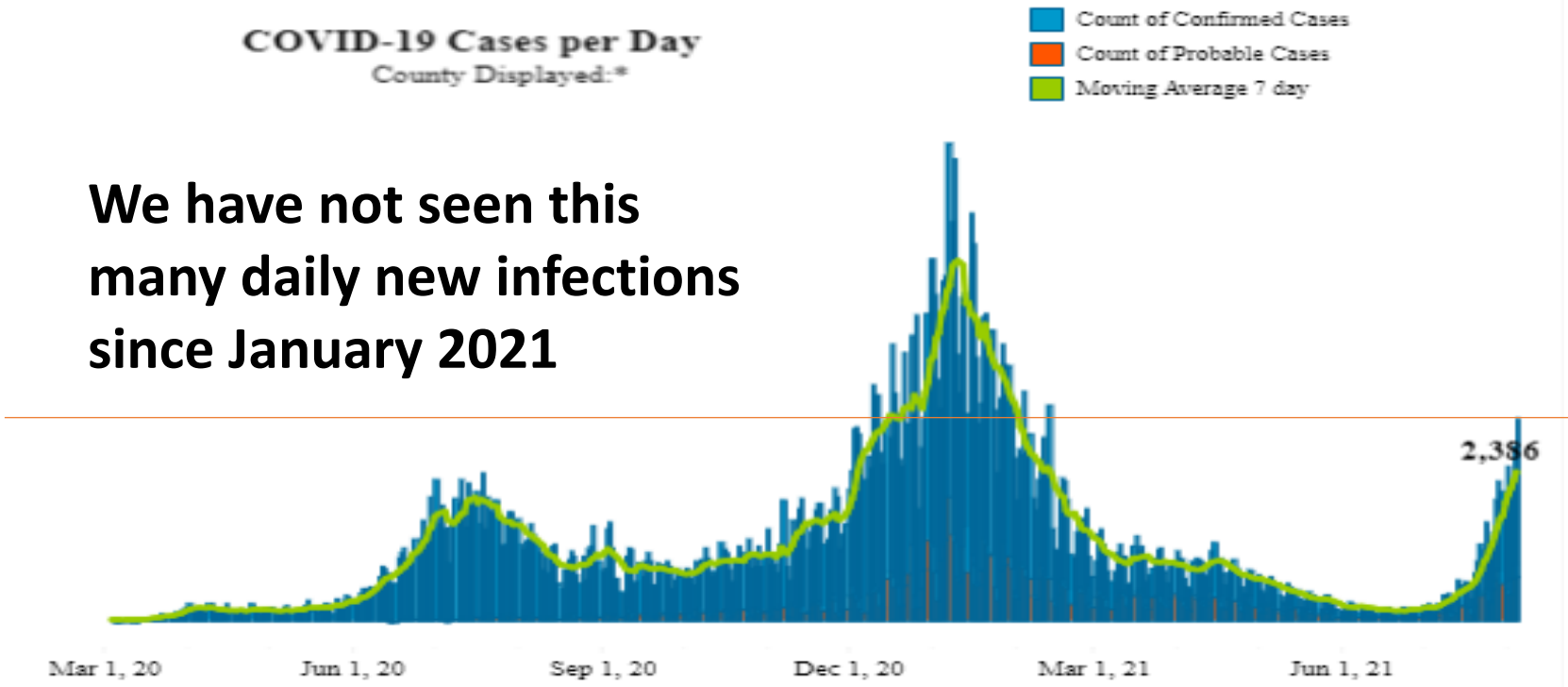


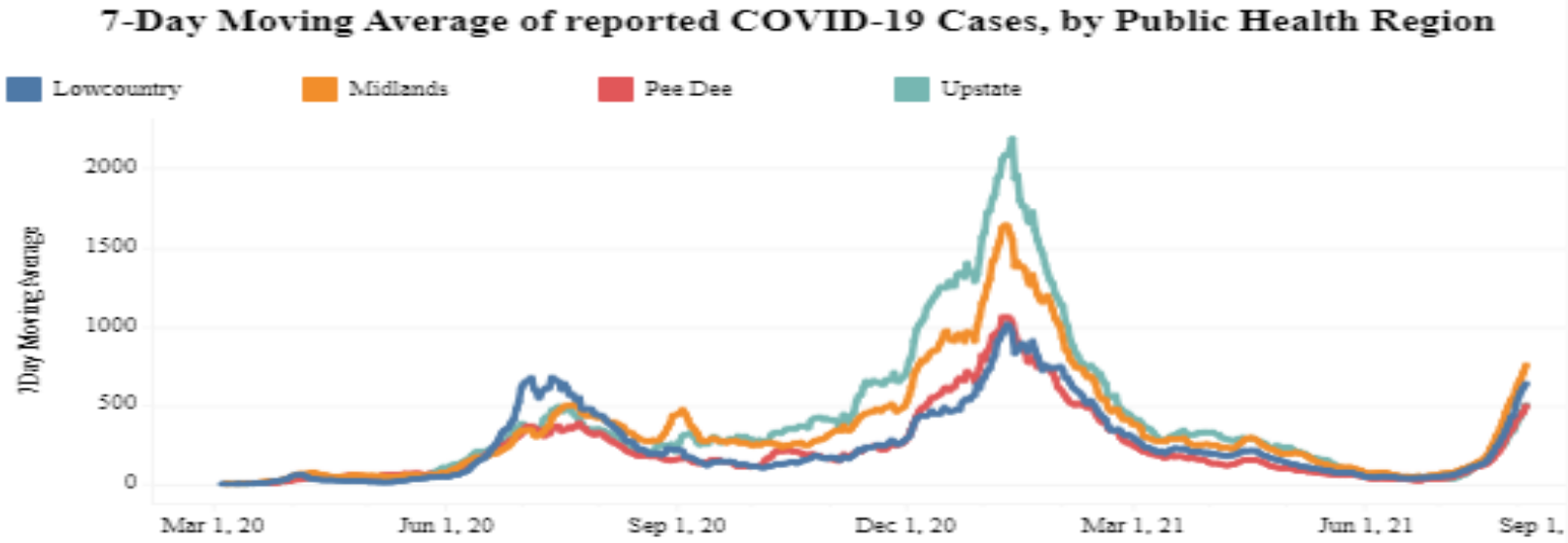
CDC | Data as of: August 8, 2021 12:25 PM ET. Posted: August 8, 2021 2:00 PM ET

Download Data

State/Territory	Level of Transmission	7-Day Case Rate per 100,000	7-day Percent Positivity
Louisiana	high	693.2	15-19.9%
Florida	high	627.4	20-24.9%
Arkansas	high	502.4	10-14.9%
Mississippi	high	436.2	20-24.9%
Alabama	high	405.8	20-24.9%
Oklahoma	high	338.2	20-24.9%
Missouri	high	330	10-14.9%
Georgia	high	301.3	15-19.9%
Tennessee	high	301	
Virgin Islands	high	287.5	10-14.9%
South Carolina	high	282.1	15-19.9%
Texas	high	267.9	15-19.9%

We have not seen this many daily new infections since January 2021





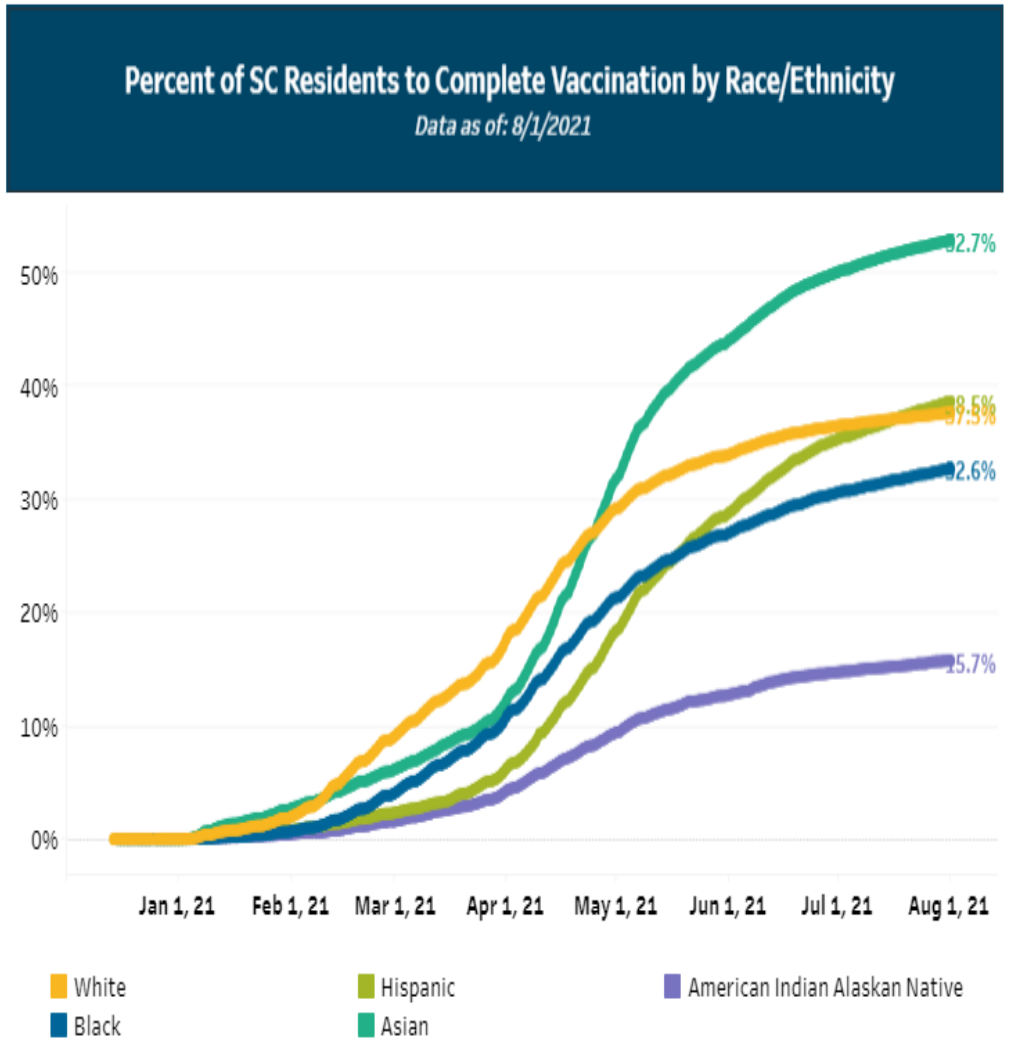
Two Week Cumulative Incidence Rate

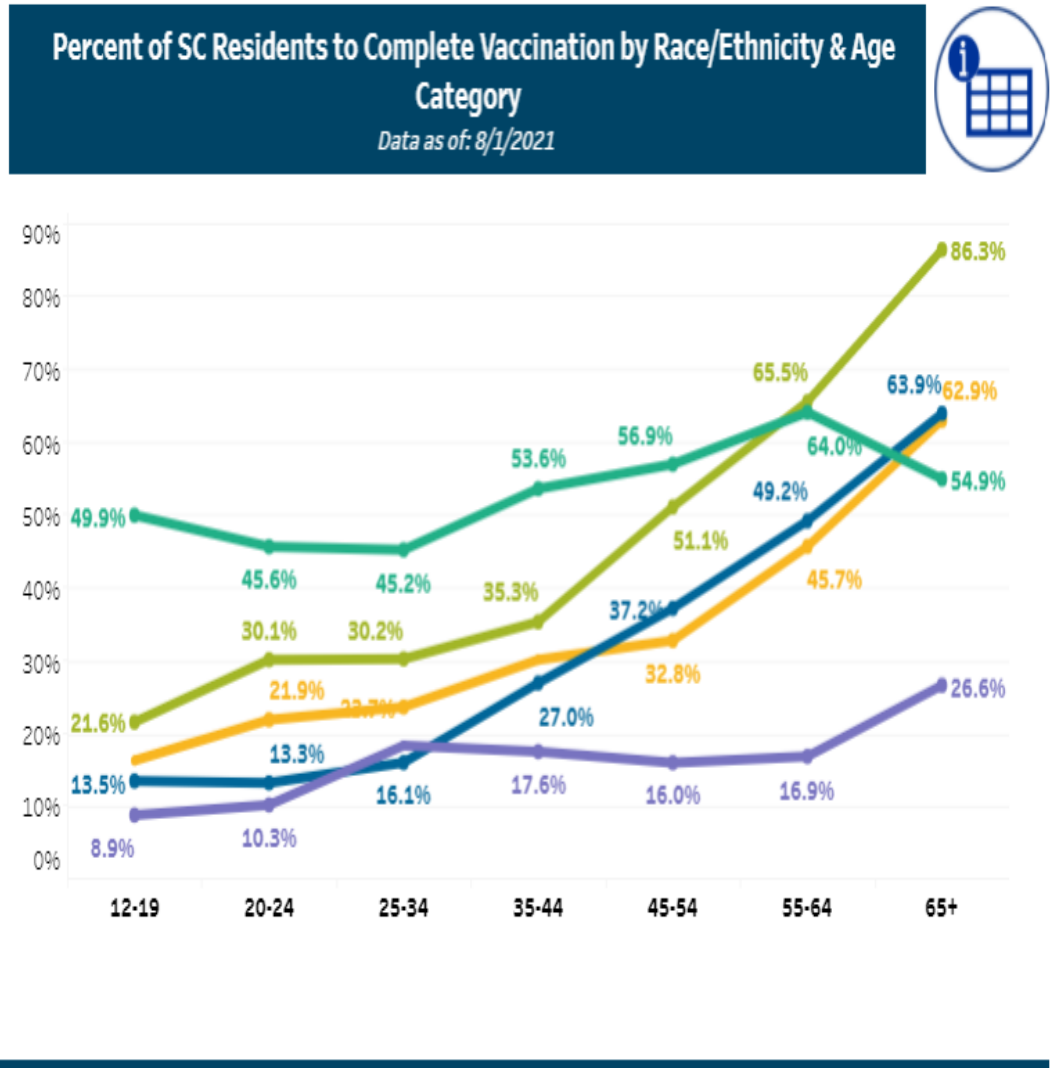
The Two-Week Cumulative Incidence Rate includes new (confirmed & probable) cases reported in the past two weeks (7/25/2021 - 8/7/2021) per 100,000 people. The rate describes recent incidence of COVID-19 infection to capture the potential burden of currently ill people who may be infectious and/or accessing healthcare.

Select a county to display county-specific information

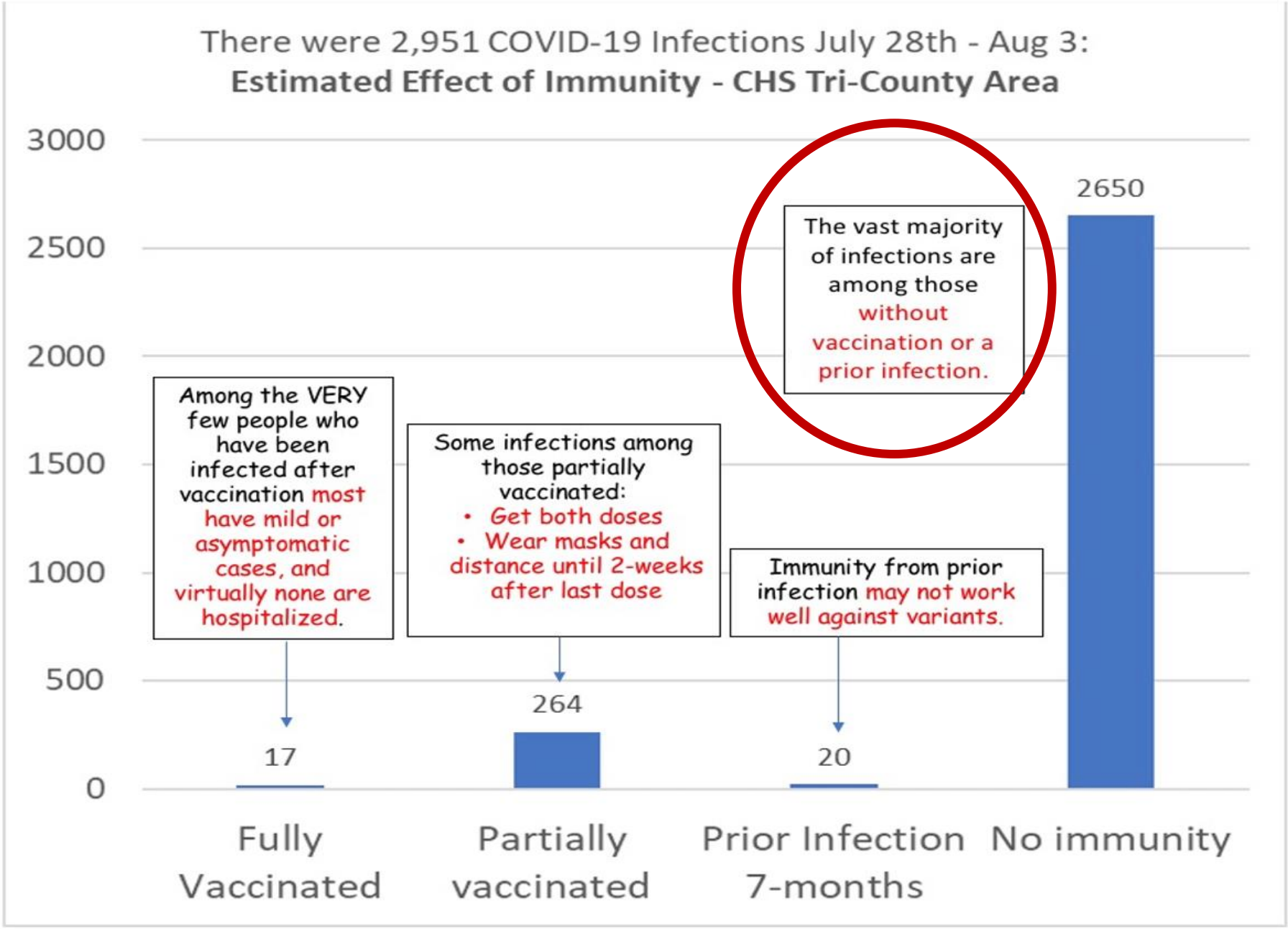
Click the county again to return to the full state map

Low; 0-50	Moderate; 51-200	High; >200





https://scdhec.gov/index.php/vaccine-reach-local-vulnerability



https://web.musc.edu/coronavirus-updates/epidemiology-project

If prior infection, no need for vaccine?

- MMWR Aug 6, 2021 case control study
- Compared Kentucky residents infected with SARS-CoV-2 in 2020 and reinfected May-June 2021 to those not re-infected
- Being unvaccinated was associated with 2.34 times the odds of reinfection compared to those fully vaccinated
- And this was before Delta was the predominant variant

TABLE 2. Association of SARS-CoV-2 reinfection* with COVID-19 vaccination status — Kentucky, May–June 2021

	No. (%)		
Vaccination status	Case-patients	Control participants	OR (95% CI)†
Not vaccinated	179 (72.8)	284 (57.7)	2.34 (1.58–3.47)
Partially vaccinated¶	17 (6.9)	39 (7.9)	1.56 (0.81–3.01)
Fully vaccinated§	50 (20.3)	169 (34.3)	Ref
Total	**246 (100)**	**492 (100)**	—

http://dx.doi.org/10.15585/mmwr.mm7032e1

If prior infection, YES need for vaccine!

- **Antibody responses elicited by natural infection vs. vaccination differ**
- **Antibody responses from infection vary with severity of disease**
- **Vaccination-elicited antibodies targeted a broader range of epitopes within the receptor binding domain (RBD) of spike protein than infection-elicited antibodies.**
- **Vaccine induces greater binding breadth**
  - **That means single RBD mutations have less impact on neutralization by vaccine sera compared to convalescent sera.**

https://stm.sciencemag.org/content/13/600/eabi9915.abstract

New Guidance for COVID Vaccination in Pregnant Women

- *"Unlike the original COVID that we were seeing 18 months ago, this new delta variant is affecting our pregnant moms more severely. We're seeing that moms who are getting affected — particularly with delta — are more likely to end up hospitalized. They're more likely to end up with severe disease and end up in the ICU. More likely to need higher-grade respiratory support… and unfortunately we're also seeing an increased risk of maternal death."*

- *"From the pregnancy side we are also seeing increased complications. Those complications include preterm birth and prematurity, increased risk of preeclampsia for these moms, which can require preterm delivery. And, unfortunately, also increased risk of stillbirth."*

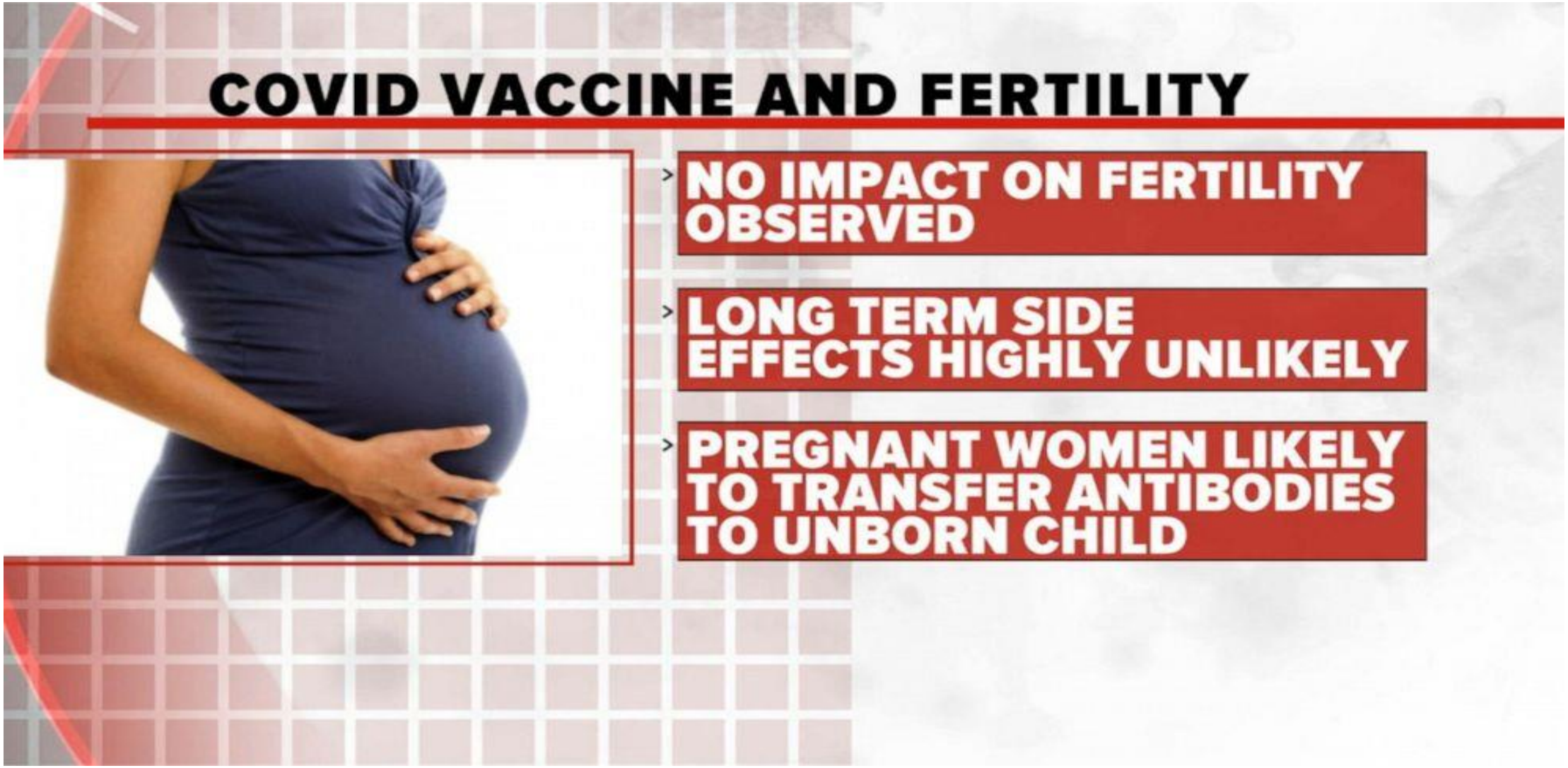
  - *DR. JESSICA EHRIG, BAYLOR SCOTT AND WHITE MEDICAL CENTER*

New Guidance for COVID Vaccination in Pregnant Women

- " Pregnancy is independently associated with a 3-fold increased risk for ICU admission, 2.4-fold increased risk for needed ECMO and a 1.7-fold increased risk of death due to COVID compared with symptomatic non-pregnant patients."
- "COVID-19 vaccination is the best method to reduce maternal and fetal complication of COVID infection among pregnant people."
  - William Grobman, MD, SMFM President
- "It is clear that pregnant people need to feel confident in the decision to choose vaccination, and a strong recommendation from their OB/GYN could make a meaningful difference for many pregnant people"
  - Martin Tucker, MD, ACOG President

New Guidance for COVID Vaccination in Pregnant Women

- New recommendation from ACOG and SMFM that **all** pregnant individuals be vaccinated against COVID-19
- Strong evidence of the safety and effectiveness of vaccination during and after pregnancy and that COVID infections put pregnant individuals and their fetus/newborn at much greater risk of major complications
- ACOG now encouraging all of its members to <u>enthusiastically</u> recommend vaccination
- Newly updated vaccination and pregnancy conversation guide for clinicians that includes:
  - special considerations for communities of color
  - continued support for pregnant patients that choose not to be vaccinated including guidance on proper masking, physical distancing and reconsideration of vaccination



During the Pfizer vaccine studies, 23 women volunteers became pregnant, and the only one who suffered a pregnancy loss was in the placebo group

Responding to vaccine hesitancy: How to talk to patients about the COVID vaccine

- CDC has recommended five techniques for healthcare practitioners to discuss COVID vaccines with their patients:
  - Actively listen
  - Use patient-centered communication with open ended questions
  - Empathetically respond to question/concerns
  - Give a strong vaccination recommendation
  - Close the conversation ensuring they know you are open to talks again if desired

Responding to vaccine hesitancy: How to talk to patients about the COVID vaccine

- **C-LEAR** approach to patient communication:
  - **C**ounsel- first step in vaccine discussion is to introduce the vaccine with a strong statement of its safety and efficacy evidence base
  - **L**isten- actively listen to all patient questions and concerns, engaging with the patient from their perspective is key to breaking down hesitancy
  - **E**mpathize- demonstrating clinical empathy toward the patient after the question or concern is critical to overcoming hesitancy, using specific empathy skills like restating, acknowledging, normalizing and/or validating
  - **A**nswer- give a brief and accurate answer to each face patient's questions and concerns
  - **R**ecommend- immediately after giving answers, reinforce the importance of the vaccine by recommending vaccination

Monoclonal Antibody Treatment Program- Key Updates

- Multiple analyses have shown that REGEN-COV is effective against the delta variant and other variants of concern
- Newly approved dosage of Caserivimab 600mg + Imdevimab 600mg is the same for IV infusion and subQ injection (1 vial = 1 patient dose)
- Distribution and use of Bamlanivimab+Etesevimab is still paused by FDA and ASPR
- MAB eligibility criteria include women during and after pregnancy and partially and fully vaccinated individuals with confirmed symptomatic COVID
- Timeliness of treatment is the most important factor in successful treatment which reinforces the value of having the subQ administration option
- New indication for post-exposure prophylaxis just approved under FDA EUA on July 30th

SC Monoclonal Antibody Utilization Summary

- Over **11,000** patients with symptomatic COVID successfully treated to date in SC
- Only 20 patients unable to complete treatment with no documentation of anaphylactic reaction or other serious adverse event
- Major ramp up in patients receiving mAB treatment over past 2 weeks mirroring delta variant surge
- Estimated number of COVID hospital admissions prevented **≥ 1380**
- Estimated number of COVID deaths prevented to date **≥ 175**